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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/738,412 | 12/17/2003 | Michelle D. Hines | SC65U-US | 8911 |

60723 7590 11/26/2007

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| EXAMINER | |
|---|---|
| CLAYTOR, DEIRDRE RENEE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 11/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/738,412 | HINES ET AL. | |
| | Examiner | Art Unit | |
| | Renee Claytor | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 23-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's arguments filed on 9/18/2007 have been fully considered. Claims 23-27 are pending, claims 1-22 and 28-57 are cancelled and claim 23 is amended herein.

Applicant's arguments over the 35 USC 103 rejection have been fully considered and are not found persuasive. Applicants argue that a prima facie case of obviousness was not established over the combination of the Wagle et al. in view of Gould. Applicants state that the statement in the Office Action that it "is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification" is legally incorrect and does not constitute a rationale for making such a modification. Applicants further argue that there is no rule per se that a prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities and that true homology does not include a substitution of methyl for hydrogen.

In response to the above arguments, it is stated in the MPEP § 2144.09 that a "prima facie" case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities". It is further stated that "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). The

MPEP further teaches that homologs include compounds differing by the successive addition of the same chemical group, e.g., by –CH2- groups. Furthermore, the composition of the present application is for cosmetic use and it is intended to be applied to the skin for improving the texture and elasticity of the skin (as taught in the specification). The compositions taught by Wagle et al. are intended for improving the elasticity or reducing wrinkles of the skin (paragraph 0007). Therefore, considering the art as a whole, there is a prima facie case of obviousness because of the close structural similarity between the present composition and the composition of the prior art, there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious).

Applicants argue that there is no motivation to modify Wagle because it was indicated in the first Office Action that it would not be predictable that the instant composition would have similar properties as the closest compounds of Wagle et al. Applicants also argue that the instant specification provides data showing that the claimed composition possess the unexpected property of inhibiting glucose oxidase. Applicants argue that the MPEP states that this unexpected use is not contemplated by Wagle and that a use and unexpected property of a composition cannot be ignored.

In response to the above arguments, Applicants previously claimed a compound having various substitutions of which would change the structure of the compound. Because Applicant's showed date for one compound (2-amino-4,5-dimethylthiazole), date was not provided for all compositions that were being claimed. In regard to the

argument of the unexpected property of the composition inhibiting glucose oxidase and that the unexpected property cannot be ignored, it is noted that the MPEP § 2144.09 teaches that "a claimed compound may be obvious because it was suggested by, or structurally similar to, a prior art compound even though a particular benefit of the claimed compound asserted by the patentee is not expressly disclosed in the prior art" and "if the prior art compound does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed compound from the prior art" *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

Applicant's amendments to the claims have necessitated the following modified grounds of rejection given below.

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Wagle et al. (US Pg-Pub 2002/0022622) in view of Gould (Int J Pharmaceutics, 33 (1986) 201-217).

Wagle et al. teaches pharmaceutical compositions that meet the limitation of the 2-amino-4,5-dimethylthiazole of claim 1. In particular, Formula I in paragraph 0004 corresponds to 2-amino-4,5-dimethylthiazole when J is sulfur, $R^a$ and $R^b$ are alkyl and R is amino (meeting the limitations of claim 23). Though this particular compound is not stated within the reference, two closely related compounds are specifically stated which are 2-amino-5-methylthiazole and 2-amino-4-methylthiazole. It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Lincoln, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942). The compositions are further formulated with pharmaceutically acceptable salts (meeting the limitation of claim 23-26; paragraph 0125, 0248, and claim 1).

Wagle et al. do not specifically teach the hydrochloride salt or the weight percentages of the composition.

Gould et al. teaches that salt formation provides a means of altering the physicochemical and resultant biological characteristics of a drug without modifying its chemical structure and teaches that hydrochloride is an FDA-approved commercially marketed salt (Table 1).

Furthermore, it is obvious to vary and/or optimize the amount of 2-amino-4,5-dimethylthiazole provided in the composition, according to the guidance provided by Wagle et al., to provide a composition having the desired properties such as the desired percentages that will effectively treat a disease or a condition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is respectfully pointed out that the recitation "cosmetic composition for topical application to the skin for inhibiting glucose oxidase" and "wherein said 2-amino-4,5-dimethylthizaole or salt thereof is present in an effective amount for inhibiting glucose oxidase when applied topically to the skin" in claim 23 has not been given patentable weight because the recitation occurs in the preamble and the intended use is not afforded patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951). Furthermore, the claims are being treated as composition claims and the intended use of the composition is not afforded patentable weight.

According to the teachings of Wagle et al., it would be obvious to formulate a composition comprising 2-amino-4,5-dimethylthiazole because Wagle et al. teaches compounds that differ from the presently claimed composition by only a methyl group. Accordingly, it would be obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Wagle et al. with Gould et al. because Gould et al. teach that hydrochloride is an FDA-approved commercially marketed salt. One would be motivated to modify the compounds of Wagle et al. with a reasonable expectation of

success because the compounds are all taught for treating skin elasticity. One would be motivated to combine the references and add the hydrochloride salt to 2-amino-4,5-dimethylthiazole in an effort to stabilize the compound.

***Conclusion***

No claims are allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER